

NON-TECHNICAL ABSTRACT

This study is sponsored Memgen, LLC and is intended as a potential treatment for patients with chronic lymphocytic leukemia (CLL), a cancer that is still incurable. This study will be conducted at MD Anderson Cancer Center, Houston, Texas to assess the safety and potential clinical benefit of this novel immunostimulatory therapy. To participate in this study, male or female patients with or without previous chemotherapy for CLL should be at least 18 years of age.

Up to 18 leukemia patients will be enrolled in this study. The study has four major phases:

1. Each patient undergoes leukapheresis, a routine process that removes leukemia cells from the blood and collects these cells.
2. The leukapheresed cells are exposed to a genetically altered adenovirus (i.e., a modified form of the virus commonly associated with colds and other respiratory illnesses). The altered adenovirus contains a normal gene that directs the leukemia cells to produce CD154, a protein molecule that activates the immune system and allows the body to fight the leukemia.
3. Each patient's modified leukemia cells that now contain the altered adenovirus are re-infused intravenously into the same patient.
4. Each patient is monitored for safety and for potential clinical responses through a series of assessments.

The actual study treatment consists of a single intravenous infusion of the patient's own modified leukemia cells. Patients will return to the clinic to be evaluated at specific timepoints for approximately two months. Thereafter, patients and/or their physicians will be contacted at quarterly intervals to find out about their CLL status, general health status, newly diagnosed diseases, and CLL related treatments they might have received.